

REMARKS

The Examiner is thanked for the due consideration of the application. A substitute abstract has been provided. The specification has been amended to improve the format.

Claims 19-22, 24-29, 31, 33 and 34 are pending in the application. By this amendment claims 23, 30, 32, 35, 36 and 37 have been canceled. Claim 19 has been amended to generally incorporate limitations from the canceled claims. Claims 20-22, 24-29, 31, 33 and 34 have been amended to improve their language in a non-narrowing fashion.

No new matter is believed to be added to the application by this amendment.

Rejection Under 335 USC §112, Second Paragraph

Claim 37 has been rejected under 335 USC §112, second paragraph as being indefinite. This rejection is respectfully traversed.

Claim 37 has been canceled, thereby rendering this rejection moot. The pending claims are set forth in language that is clear, definite and has full antecedent basis.

This rejection is believed to be overcome, and withdrawal thereof is respectfully requested.

Rejections Based on ULDALL

Claims 19-22 and 32-34 have been rejected under 35 USC §102(b) as being anticipated by ULDALL. Claims 23, 24 and 36 have been rejected under 35 USC §103(a) as being unpatentable over ULDALL in view of GRIEGO et al. Claims 25-29 and 31 have been rejected under 35 USC §103(a) as being unpatentable over ULDALL in view of BALBIERZ et al. Claims 30 and 35 have been rejected under 35 USC §103(a) as being unpatentable over ULDALL in view of PORTER. Claim 37 has been rejected under 35 USC §103(a) as being unpatentable over ULDALL in view of BALBIERZ et al., and further in view of GRIEGO et al.

These rejections are respectfully traversed.

The present invention pertains to an infusion system that is illustrated, by way of example, in Figure 1 of the application, which is reproduced below.

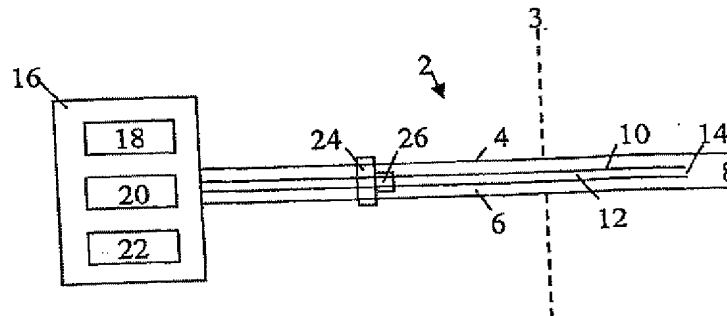
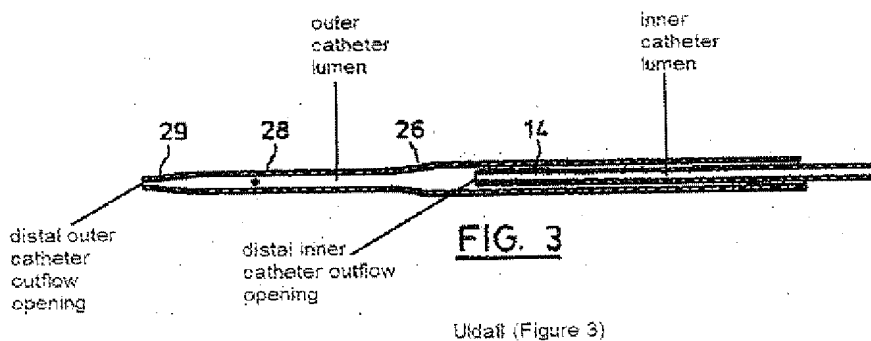


Fig. 1

Figure 1 shows a catheter 2 having an outer lumen 6 and an inner lumen 12. An external pump 16 includes a pumping means 16, a reservoir means 20 and a control means 22. The control means 22 controls the pumping means 16 such that a liquid substance is administered to a patient, where the liquid substance is followed in time by a flushing liquid. These aspects of the present invention are reflected in independent claim 19.

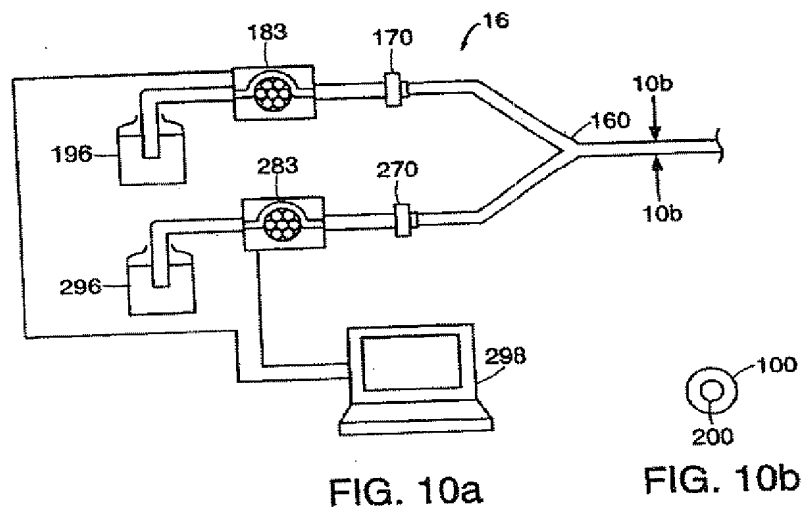
ULDALL pertains to a hemodialysis cannular. The Official Action refers to an annotated Figure 3 of ULDALL, which is reproduced below.



ULDALL fails to disclose an *infusion system*, which includes a pumping means, a reservoir means and a control means, where the control means controls the pumping means such that a liquid substance is administered to a patient, where the liquid substance is followed in time by a flushing liquid.

ULDALL thus fails to disclose each and every aspect of claim 19 of the present invention. ULDALL thus fails to anticipate claim 19 of the present invention. Claims depending upon claim 19 are not anticipated by ULDALL for at least the above reasons.

The Official Action acknowledges that ULDALL is silent about whether the substance is administered as a pulsed flow sequence of substance including a predetermined number of liquid pulses, where each liquid pulse is a predetermined number of liquid pulses. The Official Action then refers to Figures 10a and 10b of GRIEGO et al., which are reproduced below.



In the delivery system 16 shown in FIG. 10a of GRIEGO et al., a first pump 183 may be connected to and in fluid communication with the first elongated member 100 and the first lumen 120 through connection port or seal 170 and joint 160. A second pump 283 may be connected to and in fluid communication

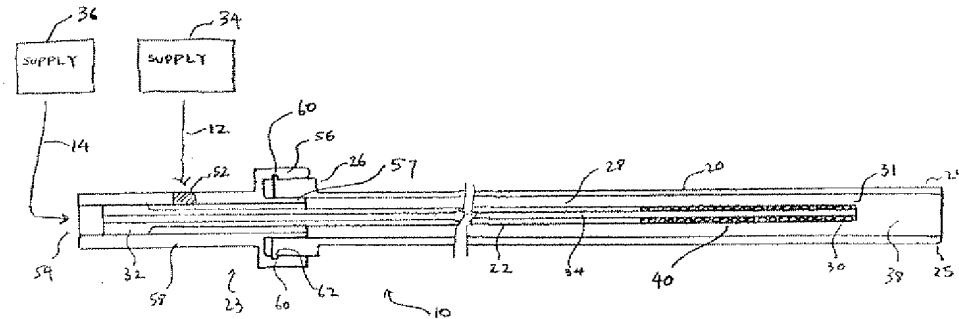
with the second elongated member 200 and lumen 220 through connection port or seal 270 of joint 160. Similar to pressure control through injectors, the pressure and material flow in the first and the second lumens 120 and 220 may be controlled by the pumps 183 and 283. Reservoirs 196 and 296 are connected to pumps 183 and 283 respectively to supply the first and second materials to the lumens 120 and 220 of elongated members 100 and 200 (FIG. 10b), respectively.

The Official Action refers to Column 9, lines 19-43 of GRIEGO et al. Regarding flow control, this passage states: "Any types of pumps may be used as long as the purpose of **controlling pressure and effecting material delivery** is achieved. A pump can be advantageously used with a typical syringe in effecting a **continuous delivery**. Such automated syringes or injectors are well known in the art. Automated and/or computerized **control of the pressure and material flow** may also be achieved through a control system 298 by incorporating appropriate computerized equipment and software."

GRIEGO et al. thus teach controlling pressure and continuous delivery. There is no teaching or inference in GRIEGO et al. of administering sequences of pulses. GRIEGO et al. additionally fail to teach a flushing sequence using the sequences of pulses.

The Official Action further acknowledges that ULDALL fails to teach a liquid pulse of the active substance through the

inner catheter lumen is followed in the time sequence by a liquid pulse of a flushing liquid applied through the outer catheter lumen. The Official Action turns to Figure 1 and paragraph 0061 of to PORTER. Figure 1 of PORTER is reproduced below.



Paragraph 0061 of PORTER states: "[T]he first fluid component 12 may be introduced to fill the first lumen 28 to the point of the mixing zone 38 (i.e. to near the tip 31 of the inner tubular element 22), and then the second fluid 14 component may be introduced to fill the second lumen 34 to the point of the mixing zone 38 (i.e. to near the tip 31). **Each of the fluid components 12 and 14 may be radiopaque so that fluoroscopic visualization may be used to monitor the progression of each fluid component.**"

PORTER fails to teach or infer a flushing liquid. PORTER instead teaches mixing reagents.

The Official Action refers to BALBIERZ for teachings pertaining to connectors and lumens. However, these teachings of

BALBIERZ fail to address the deficiencies of the other above-described applied art references in teaching or inferring claim 19, which sets forth an infusion system configured to administer a pulsed flow sequence of liquid substance via a predetermined number of liquid pulses, where each liquid pulse is a predetermined volume of the substance, and that a liquid pulse of the liquid substance through the inner catheter lumen is followed in time sequence by a liquid pulse of a flushing liquid applied through the outer catheter lumen, in order to make the liquid substance reach a target area of administration.

One of ordinary skill and creativity would thus fail to produce a claimed embodiment of the present invention from a knowledge of ULDALL in any combination of the secondary references. A *prima facie* case of unpatentability has thus not been made.

These rejections are believed to be overcome, and withdrawal thereof is respectfully requested.

Conclusion

The Examiner is thanked for considering the Information Disclosure Statement filed June 15, 2006 and for making an initialed PTO-1449 Form of record in the application.

Prior art of record but not utilized is believed to be non-pertinent to the instant claims.

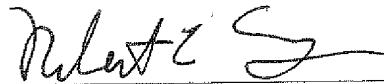
The rejections are believed to have been overcome, obviated or rendered moot, and no issues remain. The Examiner is

accordingly respectfully requested to place the application in condition for allowance and to issue a Notice of Allowability.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

The Appendix includes the following item(s):

- ☐ - a terminal disclaimer
- ☐ - a 37 CFR 1.132 Declaration
- ☒ - a new or amended Abstract of the Disclosure
- ☐ - a Replacement Sheet for Figure of the drawings
- ☐ - a Substitute Specification and a marked-up copy of the
originally-filed specification
- ☐ - a verified English translation of foreign priority document